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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,813	07/12/2001	Scott I. Klein	P24448-D US1	1787

7590 03/20/2003
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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/20/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/903,813

Applicant(s)
Klein

Examiner
David Lukton

Art Unit
1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 7, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Pursuant to the directives of paper No. 10 (filed 1/7/03), claims 22-23 have been cancelled.
Claims 20-21 remain pending.

Applicants arguments filed 1/7/03 have been considered and found not persuasive.

※

The specification is objected to because of an informality. The abstract should be revised to reflect the subject matter now claimed. Applicants attempt to overcome this objection is acknowledged. However, the abstract should be supplied on a piece of paper which contains no text other than the abstract.

※

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. §102(b) as being anticipated by Klinger (USP 5,399,570).

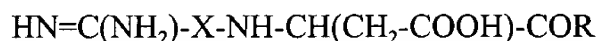
As indicated previously, Klinger discloses (col 13, line 58) the following compound:

Sar-Asp(OBz)-3,3-diphenylpropylamide

This corresponds to applicants' variables as follows:

F' = hydrogen;
G = substituted aralkyl;
B = methyl;
X = hydrogen

In response to this, applicants have argued that the examiner has misinterpreted the disclosure of Klinger. Consider first the genus that is disclosed by Klinger. This may be found at col 1, line 9+:

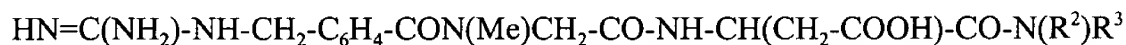


As stated col 3, line 62, substituent variable "R" is preferably $\text{N}(\text{R}^2)\text{R}^3$, and what is preferred for $\text{N}(\text{R}^2)\text{R}^3$ is an amino(C_{1-8})alkyldiphenyl radical. Consider next what variable "X" can be. As stated at col 4, line 16+

"particularly preferred radicals X are:



Thus, if one inserts this preferred "radical" for "X" into generic formula I, and insert also the preferred substituent for variable "R" [i.e., $\text{N}(\text{R}^2)\text{R}^3$], one obtains the following:



What applicants have argued is that the invention Klinger really intended to disclose (but failed to disclose) is compounds which contain a hydrazine group, or a hydrazide group. Notably, however, there is no evidence of such. There is not a single example of a structure containing a hydrazine group, not a single example of a structure containing a hydrazide group, and not a single *name* of a compound that contains the term hydrazine or hydrazino or hydrazide. At the same time, there are several structures of compounds that contain a sarcosine moiety, in which the nitrogen atom (of the sarcosine moiety) is bonded to carbon atoms only (see, e.g., col 1, line 17+; col 4, line 18+; col 4, line 24+; col 6, line 10+). In addition, there are several compounds named which contain the term "sarcosine". In each of these named compounds, the nitrogen atom (of the sarcosine moiety) is bonded to carbon atoms only.

In the passage originally cited by the examiner (col 13, line 58), the following compound is reacted with *para*-nitro guanidino-methylbenzoic acid:



Applicants have concluded that what Klinger really intended to disclose and claim was hydrazides. Applicants have concluded this because of the "H₂N" moiety tacked onto the N-terminus of a few of the amino acid derivatives. While this denotation is not really correct, it is a common error. To take a simple example, suppose that a chemist wanted

to denote the tripeptide Arg-Gly-Asp. Either of the following could be used:

Arg-Gly-Asp

H-Arg-Gly-Asp-OH

However, the denotation that some chemists and biologists will use is either of the following:

H₂N-Arg-Gly-Asp-OH

H₂N-Arg-Gly-Asp

This is not correct, but again, is a common error. Klinger has made this error elsewhere in the patent. For example, at col 13, line 17, the "H₂N-" designation has been tacked on to an aspartic acid derivative. Notwithstanding the foregoing, the examiner will grant that if a denotation such as "H₂N-Arg-Gly-Asp" or "H₂N-Asp-OH" is provided in a total vacuum, i.e., without any explanation or context, such a designation might create some ambiguity. But given the wealth of information conveyed in the patent, there is no ambiguity.

The rejection is maintained.

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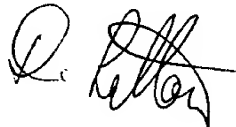
- 6 -

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


DAVID LUKTON
PATENT EXAMINER
GROUP 1653